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Author: **Phil Noll**		

Environmental Stewardship—
Environmental Characterization and Remediation

Quality Procedure

for # Standard Operating Procedure Development

Revision Log

Revision No.	Effective Date	Prepared By	Description of Changes	Affected Pages
R0	2/27/98	John L. Day	New quality procedure (QP); replaces administrative procedures (APs) AP-01.1 and AP-01.5	All
R1	8/27/98	John L. Day	Format and process changes	All
R2	8/27/99	John L. Day	Format and process changes	All
R3	5/9/01	Andrew Gallegos	Revised to incorporate revision log page; section 2.0, Scope; section 3.0, References; new sections to address interim change notices (ICNs), lessons learned, Price-Anderson Amendments Act of 1988 (PAAA) and integrated safety management (ISM) requirements, and periodic procedure review requirements.	All
R4	12/10/02	Andrew E. Gallegos	Revised to incorporate ICN ER2001-0480, use of process flow charts, and format changes. Added Attachment B, "Quality Procedure Deletion Action Request," and information about development and submission of forms. Format changes included new Environmental Restoration Project logo deletion, table of contents page, and use of *shall, will, must,* and *should*. SOP template and QP rewritten and restructured so that QP functions as instructions for template.	All
Reviewed	05/06/2004	Phil Noll	Process deemed adequate.	
R5	10/6/05	Phil Noll	Revised to incorporate organizational and programmatic changes, NES requirements, change number of allowable ICNs to 4, and extend review period one year.	10/6/05

Standard Operating Procedure Development

Table of Contents

List of Acronyms and Abbreviations

AP	administrative procedure
DCC	Document Control Coordinator
DSA	Documented Safety Analysis
ERS	environmental restoration and surveillance
ICN	interim change notice
ISM	integrated safety management
LANL	Los Alamos National Laboratory
NES	Nuclear Environmental Site
PAAA	Price Anderson Amendments Act
PPE	personal protective equipment
PL	Project Leader
QP	quality procedure
QPPL	Quality Program Project Leader
RPF	Records Processing Facility
S&M	Surveillance and Maintenance
SOP	standard operating procedure
SSHASP	site-specific health and safety plan
TSR	Technical Safety Requirements
USQ	Unreviewed Safety Question

1.0 PURPOSE

This Quality Procedure (QP) states the resposibilities and describes the process for the developing, revising, creating ICNs, or deleting SOPs; and/or implementing periodic reviews of SOPs for the Los Alamos National Laboratory (LANL), Environmental Restoration and Surveillance (ERS) Project.

Note: The process for requesting a QP action (e.g., developing, revising, creating ICNs, or deleting QPs, and/or implementing periodic reviews of QPs) is covered in QP-4.1.

2.0 SCOPE

2.1 All **ERS personnel** shall implement this mandatory QP for the ERS Project.

2.2 **Subcontractors** performing work under the ERS Project's quality program shall follow this QP.

3.0 TRAINING

3.1 All **ERS personnel** shall train (i.e., read-only training) to and use the current version of this QP. Contact the author of this QP if the text is unclear.

3.2 All **ERS personnel** using this QP shall document training in the training database is located at http://erinternal.lanl.gov/Training/login.asp in accordance with QP-2.2.

3.3 The appropriate **supervisor** shall monitor the proper implementation of this procedure and ensure that the appropriate personnel complete all applicable training assignments.

4.0 DEFINITIONS

4.1 *Action step*—A procedure element that provides instruction for performing a specific process action or task.

4.2 *Action substeps*—Detailed actions that make up the upper-level action step or that describe how to perform the action step.

4.3 *Author*—The technical expert who owns the process described within the QP and who retains ultimate responsibility for the technical content.

4.4 *Document Control Coordinator*—The person responsible for maintaining and managing the ERS Project document control master list, formatting controlled electronic files for web publication, and ensuring that each QP is reviewed every two years.

4.5 *Effective date*—The date on which a procedure is sent for web publication.

4.6 *Identifier*—A unique number assigned to a procedure by the DCC to categorize, identify, and control the procedure.

4.7 *Interim Change Notice*— Notification of procedure changes that are more narrow in scope than those of a major revision.

4.8 *Major revision*—Changes to a procedure that affect the technical content or process of the work.

4.9 *Minor revision*—Changes to a procedure (e.g., grammar or spelling corrections, renumbering sections or attachments, changing the title or document number, or updating organizational changes, etc.) that do not affect the technical content or process of the work.

4.10 *Process flow chart*—A tool used in complex procedures to enable the user to visually track action steps within the procedure or move on to other documents.

4.11 *Quality procedure*—Within the ERS Project, a document that describes the process for performing any activity governed by the ERS Project Quality Management Plan.

4.12 *Requester of a SOP action*—Any ERS member who requests the development of a new SOP, the revision of an existing SOP, or the deletion of an existing SOP.

4.13 *Standard Operating Procedure*—A document that describes the operations, analyses, or actions that are the commonly accepted method for performing certain routine or repetitive tasks (i.e., generally field-implemented procedures associated with the collection of data).

5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in this procedure:

- Author
- Document Control Coordinator
- ERS personnel
- Peer Review Task Leader
- Procedure user
- Project Leader
- Quality Program Project Leader
- Requester
- Reviewer
- Subcontractor
- Supervisor
- User

6.0 PROCEDURE

6.1 SOP Action Request

ERS personnel shall request the development, revision, or deletion of a SOP by contacting the ERS Project QPPL.

6.2 New SOP Development

6.2.1 The responsible **PL** shall assign an author to develop the SOP.

6.2.2 The **author** shall obtain a new SOP number (its identifier) from the DCC, providing the SOP title and document catalog number from the Document Signature Form generated at http://erinternal.lanl.gov/DocCatalog/home.asp.

6.2.3 Before developing a SOP, the **author** should review the following documents to ensure that applicable safety requirements are identified and addressed in the SOP:

- The LANL ISM description document, LA-UR-98-2837, located at http://int.lanl.gov/safety/pdf/desc_doc.pdf.
- The Price Anderson Amendments Act (PAAA), located at http://aea.genlaw.lanl.gov/PAAA/index.html.

6.2.4 The **author** shall work with a technical editor assigned to the author's focus area/organization, if applicable, to ensure that the SOP is readable, coherent, and in compliance with ERS Program and LANL guidelines.

6.2.5 The **author** shall make a copy of the MS Word template provided at http://erinternal.lanl.gov/WritingGuide.shtml or http://erinternal.lanl.gov/Quality/user/qps.asp by opening the template and saving it with a file name that contains its document catalog number, the SOP identifying number, and the revision number (e.g., ER2002-0577QP-4.1R3.doc [no spaces]). (The template contains proper formatting, headings, and boilerplate text.)

6.2.6 The **author** shall write the SOP according to the general guidelines below:

6.2.6.1 Replace or delete the template bracketed text; the remaining text is mandatory, boilerplate text.

6.2.6.2 Express required actions by using *shall* in declarative sentences (e.g., "The **manager** shall approve the completed work order" instead of "Completed work orders are approved by the manager"). Use imperative sentences (direct commands) as illustrated throughout this SOP.

6.2.6.3 Use acronyms and abbreviations as defined in the acronym and abbreviation list located at http://erinternal.lanl.gov/WritingGuide.shtml.

- Spell out acronyms and abbreviations at their first use in text; or
- Make an alphabetical list of the acronyms and abbreviations.

Note: An alphabetical list of acronyms and abbreviations is optional based on the author's preferences.

- Insert the list just after the Table of Contents if the list is shorter than one page. If the list is longer, provide the list as an attachment to the SOP.

6.2.6.4 If a procedure is complex, consider incorporating one or more process flow charts under the following conditions:

- The chart does not replace procedural text.
- The chart helps the user better understand the action steps and subaction steps within the procedure.
- The chart is made up of standard flow chart symbols and processes (see Attachment C for examples).
- The chart is an attachment.

Note: The use of flow charts is not mandatory.

6.2.7 The **author** shall create sections as described below, leaving the template's boilerplate text intact (the boxed text indicates a required section heading).

6.2.7.1 **1.0 PURPOSE**

Insert a clear and concise description of the task or operation governed by the procedure.

6.2.7.2 **2.0 SCOPE**

Insert scope requirements as addressed in the SOP template, however, if action step 2.3 does not apply do not enter it in the SOP.

6.2.7.3 **3.0 TRAINING**

Insert training requirements and describe how to meet those requirements (e.g., read only, On the Job training [OJT] or classroom).

6.2.7.4 **4.0 DEFINITIONS**

- Do not include "how-to" instructions or cite references for defined terms.
- Add any SOP-related terms that are unique to the SOP and any terms that may be unfamiliar to the SOP user.
- Use the ERS Project glossary at http://erinternal.lanl.gov/WritingGuide.shtml for writing definitions.

Note: If a term's definition is revised and/or a new term definition developed, submit the definition to an ERS Project editor for incorporation into the ERS Project glossary.

- Order the terms and definitions alphabetically and follow the template's numbering style.

6.2.7.5 **5.0 RESPONSIBLE PERSONNEL**

List personnel (by title or role) who have responsibilities described in the SOP; order the list alphabetically.

6.2.7.6 **6.0 BACKGROUND AND PRECAUTIONS**

- Summarize any background information about the SOP activities that may clarify the activities.
- List any required precautions.

6.2.7.7 **7.0 EQUIPMENT**

- Make a checklist of all equipment and supplies needed to perform the procedural work process; add the checklist items to Attachment A of the SOP template.
- Specify the correct version of any operating manual used with the equipment; ensure that the manual is available.
- If an equipment list is not applicable, replace the boilerplate paragraph in section 7.0 with “Not applicable.”
- Use section 7.0 to provide a list of typically-used equipment and note the advantages and limitations of each (follow the format of the definitions section in this SOP).

6.2.7.8 **8.0 PROCEDURE**

- Describe the required work in clear and concise action steps, giving one action per numbered section. If the procedure is complex, group action steps together and add a descriptive subheading, as done in this document. Apply the template’s “level2text TOC” style to these subheadings and create more subheadings, as needed, to show nested subactions.
- Identify by boldfaced title the person (from the Responsible Personnel section) who performs each step.
- Include descriptions of applicable quality assurance and quality control management processes (e.g., calibration of measuring and test equipment.
- Include any safety requirements that are unique to the SOP.
- Include references to any existing documents (e.g., QP-3.4, Managing Nonconformance, Deficiencies, and Corrective Actions) that should be used to demonstrate quality or control.
-

6.2.7.9 **9.0 LESSONS LEARNED**

Add lessons learned boilerplate text and web locations as addressed in the template.

6.2.7.10 **10.0 RECORDS**

- Insert the title or role of the person responsible for record submittal.
- List the SOP-generated records that require transmittal to the ERS Project, Records Processing Facility (RPF).

6.2.7.11 **9.0 REFERENCES**

- List all documents that are cited in the SOP and all those needed for process clarity. (The SOP template already contains a set of standard documents and their online location).
- When adding a document that is available from a different web location, provide the URL.

6.2.7.12 **10.0 ATTACHMENTS**

- Include the template wording, "The user of this SOP may locate all forms associated with this procedure at http://erinternal.lanl.gov/Quality/user/forms.asp," only if all forms are online.
- Update the list of attachments in the SOP template.
- Add new attachments. If one is an online form, add it by following the example of Attachment A in the SOP template and using the appropriate watermark.
- If an attachment is a database-generated form, note that in the section 10.0 list.

6.2.8 The **author** shall ensure that the new SOP is developed, reviewed, and approved in accordance with QP-4.9 and QP-3.5.

6.2.9 It is recommended that before a SOP is submitted to the QPPL for approval, the **author** informally verify and validate (i.e., walk down) the process to ensure accuracy and ease of implementation.

6.2.10 If a walk down is performed, the **author** may elect to address the following questions:

- Are regulatory, technical, and administrative requirements addressed?
- Is the procedure written at the proper level given a typical user's experience and training (e.g., qualification)?
- Are safety and quality requirements properly addressed, as applicable?
- Are action items (tasks) properly addressed (e.g., who, when, where, and how are tasks accomplished)?

- Does the procedure present action items clearly, concisely, and in the proper sequence?
- Are forms user-friendly, and do they properly address procedural requirements?

6.2.11 If the SOP is revised as a result of the walk down, the **author** shall inform the Peer Review Coordinator of the results, including any SOP revisions that would affect previous input from the peer review panel (see QP-4.9).

6.2.12 The **author** shall sign and date the Document Signature Form, forwarding a hardcopy of the SOP, an electronic copy of the SOP, and the signature form to the QPPL for review and approval.

6.2.13 When satisfied that the SOP meets the requirements of this procedure, the **QPPL** signs and dates the Document Signature Form.

6.2.14 The **QPPL** shall complete the process by following QP-4.5.

6.3 SOP Revision

6.3.1 If a SOP requires major revision (see Section 4.8), the responsible **PL** shall ensure that the author initiates the revision by following the appropriate requirements in section 6.2 above and in QP-4.9, “Document Development and Approval.”

6.3.2 If a SOP requires only minor revisions (see section 4.9) that do not affect the technical content or process of the work, the **PL** shall ensure that the author follows QP-4.9 and QP-4.5, “Document Control.”

6.4 Interim Change Notice (ICN)

6.4.1 Before creating an ICN, the **requester** shall consult the author or responsible PTL to determine if an ICN is appropriate.

6.4.2 The **requester** shall acquire required number designators, e.g., the ICN number from the DCC, following QP-4.5 and a Document Catalog Number, acquired from http://128.165.52.52/DocCatalog/home.asp, in accordance with QP-4.9.

6.4.3 The **DCC** shall ensure that no more than four (4) ICNs are issued against a particular procedure’s revision.

6.4.4 If four (4) ICNs are issued against a particular SOP, the **DCC** shall inform the author that the SOP requires a revision, following section 6.3 of this document.

6.4.5 If an ICN is appropriate, the **requester** shall fill out a SOP ICN form located at http://erinternal.lanl.gov/Quality/users/forms.asp (see Attachment A).

6.4.6 The **requester** shall enter a justification for the ICN in block 7 of the form and ensure that the justification is consistent with the definition of ICN in section 4.7 of this document.

6.4.7 The **requester** shall obtain review and concurrence from at least one technical reviewer, as well as from the QPPL.

6.4.8 The **reviewer** shall consider the changed portion of the procedure, the effects of the changes on the procedure, and the results of implementing the changed procedure.

6.4.9 After reviewing and approving the ICN, the **QPPL** shall forward an electronic copy of the ICN and the completed Document Signature Form to the **DCC** for processing.

6.4.10 The **DCC** shall process the ICN in accordance with QP-4.5.

6.5 SOP Deletion

6.5.1 The **requester** of the deletion shall help the QPPL determine if the procedure is eligible for deletion by providing key information, for example

- the relevant procedural requirements are no longer addressed in upper-tier documents such as 10 CFR, Part 830, Subpart A; Department of Energy Order 414.1; or Laboratory Implementation Requirements;
- a particular procedure's requirements will be, or are currently, integrated into another procedure(s);
- the ERS Project is no longer required to implement the processes addressed in the procedure; and/or
- the procedure requires total revision and/or is replaced by another procedure or form.

6.5.2 After obtaining the information addressed in action step 6.5.1, and a determination is made to delete the SOP, the **QPPL** shall send a global email to all ERS personnel addressing the deletion.

6.5.3 If a procedure user objects to the deletion, that **user** shall notify the QPPL within ten working days of receiving the deletion notification.

6.5.4 After ten days, if no objection is made, the **QPPL** notifies the DCC to delete the procedure.

6.5.5 The **DCC** shall process the deleted procedure in accordance with QP-4.5.

6.6 Periodic Review of Procedures

Note: Effective October 6, 2005, the review period for SOPs has been extended for one (1) year. The extension is to institute a new process for document review and control. Training to the procedures is still required for both new hires and for requalification. If a new or revised procedure is instituted, training requirements will be addressed at that time to ensure an effective transition.

6.6.1 The **author,** or the responsible **PL,** shall review, in accordance with QP-4.5, "Document Control and Distribution", each SOP within his/her purview at least

every two years to ensure that the SOP meets current requirements, processes, regulations, standards, and/or laws.

6.6.2 The **author,** or the responsible **PL,** shall submit the procedure review form along with the associated document signature form to the DCC for processing in accordance with QP-4.5.

6.7 Deviations from SOPs

Note: Deviations from SOPs are allowed under the following circumstances:

6.7.1 For non-NES work, document deviations from SOPs in accordance with QP5.7 Notebook Documentation for Environmental Restoration Technical Activities.

6.7.2 For NES work, deviations from SOPs that impact any one, or combination of, the commitments listed in Appendix A, requires a completed Unreviewed Safety Question (USQ) screen before the deviation may take place. Deviations that do not impact the commitments listed in Appendix A may be documented in field notebooks in accordance with QP 5.7.

7.0 LESSONS LEARNED

7.1 Before performing the work described in this SOP, **ERS personnel** should go to the Department of Energy Lessons Learned Information Services home page, located at http://www.tis.eh.doe.gov/ll/ll.html, and/or the LANL Lessons Learned Resources web page, located at http://www.lanl.gov/projects/lessons_learned/, and search for applicable lessons.

During the performance of work, **ERS personnel**, as appropriate, shall identify, document, and submit lessons learned, in accordance with QP-3.2.

8.0 RECORDS

The **author** and **DCC** shall submit, as applicable, the following records to the RPF in accordance with QP-4.4 and QP-4.5:

- A hard copy of the approved new or revised SOP
- A signed hard copy of the completed Document Signature Form
- A signed hard copy of the completed ICN form, if applicable
- A signed hard copy of the completed Quality Procedure Deletion Action Request form, if applicable
- An electronic copy of the approved new or revised procedure

9.0 REFERENCES

To properly implement this SOP, **ERS personnel** should become familiar with the contents of the following documents located at http://erinternal.lanl.gov/home_links/Library_proc.shtml:

- ER Project Program Quality Management Plan
- QP-2.2, Personnel Orientation and Training

- QP-2.3, Personnel Exit and Entry Process
- QP-3.2, Lessons Learned
- QP-3.5, Peer Review Process
- QP-4.2, Standard Operating Procedure Development
- QP-4.4, Record Transmittal to the Records Processing Facility
- QP-4.5, Document Control
- QP-4.9, Document Development and Approval Process: Peer Review Required
- QP-4.10, Document Development and Approval Process: Peer Review not required
- QP-5.7, Notebook Documentation for Environmental Restoration Technical Activities
- Editing and Composition Guidelines for Preparing ERS Project Documents, located at http://erinternal.lanl.gov/WritingGuide.shtml
- Los Alamos National Laboratory Integrated Safety Management Description Document, LA-UR-98-2837, located at http://int.lanl.gov/safety/pdf/desc_doc.pdf
- Price Anderson Amendments Act, located at http://aea.genlaw.lanl.gov/PAAA/index.html

10.0 ATTACHMENTS

The user of this QP may locate all forms associated with this procedure at http://erinternal.lanl.gov/Quality/user/forms.asp.

Attachment A: Standard Operating Procedure Interim Change Notice, form and instructions (2 pages)

Attachment B: Specific Commitments made in the DSA/TSR and/or in the NES S&M Program

Using a token card, click (+control key) here to record "self-study" training to this procedure.

If you do not possess a token card or encounter problems, contact the ENV-ECR training specialist.

Attachment A

Standard Operating Procedure Interim Change Notice (ICN)

Effective Date:

Page(s)

Section 1: Description of Change (Requester completes)		1. Document Catalog No.: **ER200 -**
2. SOP & Rev. No.:	3. ICN No.:	4. SOP Title:

5. Description of Change:

6. Attachments Modified, Added, or Removed: ☐ Yes ☐ No

7. ICN Justification:

8. Requester: _____
(Print name, then sign.) (Date)

Section 2: Evaluation and Approval (Project Team Leader, Technical Reviewer, and Quality Program Project Leader complete.)

9. Evaluation Remarks: (If none, enter N/A)

10. Project Team Leader: _____
(Print name, then sign.) (Date)

11. Technical Reviewer: _____
(Print name, then sign.) (Date)

11. QPPL: _____
(Print name, then sign.) (Date)

QP-4.2, R5	**Los Alamos National Laboratory** **Environmental Restoration**

Attachment A

ICN Form Instructions

Section 1: Description of Change (Requester completes)

1. Enter the document catalog number for this ICN acquired from http://erinternal.lanl.gov/DocCatalog/home.asp.
2. Record the SOP number and revision number.
3. Record the current ICN number acquired from DCC.
4. Record the SOP title.
5. Describe the changes in detail. Provide marked-up copies of the procedure or attach additional sheets, as necessary.
6. Were procedure attachments modified, added, or removed? Check ***yes*** or ***no***. If ***yes,*** identify the affected attachments.
7. Provide a clear and concise justification for the change(s).
8. Print name, then sign and date the form.

Section 2: Evaluation and Approval (QPPL and PTL complete)

9. Either the PTL or the QPPL records any evaluation remarks; if there are none, enter ***N/A***.
10. The PTL prints name, then signs and dates the form.
11. The technical reviewer prints name, then signs and dates the form.
12. The QPPL prints name, then signs and dates the form.

Attachment B

DSA Commitments

Any deviation from an SOP that impacts one or more of the commitments listed below will require a completed USQ screen before the deviation may take place.

1) General (in several activities/tasks) – leveling/grading and surface preparation cannot remove material from cap/cover of disposal units. If leveling is required, new material needs to be brought in to allow grading
2) Access routes will be constructed through addition of new material rather than removal of existing material
3) During angle drilling, down-hole instruments are used to determine depth and trajectory of bit are as planned
4) Maximum auger diameter of 12”
5) Drilled materials need to be collected
6) Monitoring of cores and cuttings for radiological and hazardous material content as or soon after they are brought to the surface (cores are evaluated before they are opened)
7) Mud pits will not be constructed on the NES
8) No power equipment to perform soil and sediment sampling
9) Monitoring wells capped when not in use
10) Wells no longer needed will be properly abandoned, capped, and sealed
11) Trees not removed by pushing, pulling, digging etc. Only removed by cutting off and stump can be ground down to grade
12) Permanent footers not allowed for construction
13) No ground disturbing activities allowed where cover material is thin
14) Cannot permanently add radiological or hazardous materials to the NES
15) Drilling will not intrude into disposal units
16) Exhumed material will be examined as to its matrix and radiological/hazardous chemical content
17) Radioactive and hazardous chemical limits will be established
18) If the limits from the preceding item are exceeded, drilling will be stopped to determine if a disposal unit has been breached. If a unit has been breached, drilling will be permanently discontinued in that hole and an investigation will determine the cause of the breach.
19) During drilling, material will be removed at such a rate as to allow continuous or near continuous evaluation of material
20) Dust controls will be implemented to minimize hazards to worker, public, and environment